

REMARKS/ARGUMENTS

The Status of the Claims.

Claims 1-9, 11-23, 30-43, 45-71, 113 and 114 are pending with entry of this amendment, claims 10, 24-29 and 44 being cancelled herein and claims 1, 12-13, 30, 38, 45, 113 and 114 being amended herein. These amendments introduce no new matter and support is replete throughout the specification. These amendments are made without prejudice and are not to be construed as abandonment of the previously claimed subject matter or agreement with any objection or rejection of record. Because the amendments place the claims in condition for allowance, or simplify issues for appeal, entry of the amendment, pursuant to 37 C.F.R. § 1.116 is respectfully requested.

The Information Disclosure Statement.

Applicants submit herewith an Information Disclosure Statement and accompanying Form 1449 for consideration by the Examiner.

35 U.S.C. §103(a).

THE CLAIMS ARE PATENTABLE OVER YOSHIDA AND JOVANOVICH

Claims 1-9, 14, 16, 19-21, 29-38, 42-49, 53, 54 and 56-58 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Yoshida et al. (USPN 4,708,940) in view of Jovanovich et al. (USPN 6,423,536). Applicants traverse.

Three requirements must be met for a *prima facie* case of obviousness. First, the prior art reference must teach all of the limitations of the claims. M.P.E.P. § 2143.03. Second, there must be a motivation to modify the reference or combine the teachings to produce the claimed invention. M.P.E.P. § 2143.01. Third, a reasonable expectation of success is required. M.P.E.P. § 2143.02. The teaching or suggestion to combine and the expectation of success must be both found in the prior art and not based on Applicants' disclosure. M.P.E.P. §2143.

The cited publications do not teach all of the limitations of the claimed invention

Yoshida and Jovanovich, alone or in combination, do not teach all of the limitations of the claimed invention, and thus do not meet the first criterion for proving a *prima facie* case for obviousness.

The claims as amended are drawn to automated centrifuge systems having (a) at least a first rotor comprising a plurality of sample receiving regions arranged in non-vertical clusters having longitudinal axes that are substantially parallel among members of a given cluster, and (b) a plurality of sample processing components coupled to at least one transport mechanism that is configured to move member sample processing components proximal to or within each of at least two of the plurality of sample receiving regions of the rotor at substantially the same time. The sample processing components are configured to be inserted into sample vessels when the sample vessels are present in the rotor.

Yoshida is alleged to teach a system having a centrifuge rotor with a plurality of receiving regions (sample pots) and a transport mechanism (driving device and arm) configured to move a sample take-out pipe into a sample pot. Jovanovich is alleged to teach an automated centrifuge system having a microplate bucket and a transport mechanism configured to move a plurality of capillary tubes proximal to the wells of a microplate at substantially the same time.

However, Yoshida and Jovanovich (alone or in combination) do not teach all of the limitations of the claimed invention. For example, neither publication teaches or discloses an automated centrifuge system having a rotor in which the plurality of sample receiving regions are arranged in non-vertical clusters having longitudinal axes that are substantially parallel among members of a given cluster. Both the Yoshida system and the Jovanovich system employ “swinging bucket” style rotors (see Yoshida Figure 6 and Jovanovich Figure 5A, as helpfully provided by the Examiner). As such, the Yoshida and Jovanovich rotors have vertical sample receiving regions, rather than the non-vertical regions as claimed. As also indicated in the above-cited figures, the vertical “sample pots” of Yoshida and rotor platforms for receiving the sample vessel (microplate with capillary cassette) provided in Jovanovich are individual, evenly spaced sample receiving regions, not members of a plurality of sample receiving regions arranged in non-vertical clusters as in the claimed invention. Thus, neither reference teaches or describes a rotor with a plurality of sample receiving regions arranged in non-vertical clusters having longitudinal axes that are substantially parallel among members of a given cluster.

Furthermore, neither Yoshida nor Jovanovich teaches or describes sample processing components configured for insertion into sample vessels positioned in the non-

vertical clusters of sample receiving regions of the claimed rotors, much less pluralities of such components. The sample processing component (sample take out pipe 12) of Yoshida is configured for insertion into the vertical potholders of the Yoshida rotor (as clearly shown in Figures 2 and 6, and described at column 3, lines 30-33: “These pot holders are attached to the rotor 2 so that they take a vertical attitude when the rotor 2 is stationary...”). Applicants note that Yoshida figures 4 and 6 as referenced at page 18 of the Office Action are depictions of the hanging bucket rotor with the sample pots extended (figure 4, for the purpose of clarity; figure 6, showing position during rotor rotation); these figures do not depict interaction of the sample take-out pipe with the sample pot in the depicted orientation, nor are they meant to. The alleged “processing components” (capillary tubes 12) of Jovanovich are also configured to be inserted into vertically-oriented wells of a microplate positioned on the platform of the swinging bucket-type rotor (see Figure 5A). Neither reference teaches or describes pluralities of sample processing components configured for insertion into sample vessels positioned in the non-vertical clusters of sample receiving regions of the claimed rotors. Thus, the cited art does not meet the first criterion for proving a *prima facie* case for obviousness.

There is no motivation to modify the cited art to produce the claimed invention

The Office has not provided any motivation from the cited art to modify the “hanging bucket”-style rotors and sample handling elements of the prior art to produce automated centrifuge systems having both a) rotors with non-vertical clusters of sample receiving regions and b) transport mechanism-coupled sample processing components suitable for insertion and sample processing in the non-vertical sample receiving regions of the claimed rotor. Both Yoshida and Jovanovich require the use of hanging bucket-style rotors (see Yoshida column 3, lines 29-33 and Jovanovich column 11, lines 6-8); since the “hanging bucket” type of centrifuge rotor to be used has been specified in the cited art, there is no motivation to substitute a fixed angle-type centrifuge rotor, much less to alter the configuration of the aperture to provide member sample receiving regions arranged in non-vertical clusters having longitudinal axes that are substantially parallel among members of a given cluster as claimed. In addition, the Yoshida sample processing component (the “sample take-out pipe”) is designed for aspiration of individual clinical samples for subsequent analysis in the clinical analyzer; there is no motivation to employ a plurality of

sample processing components at substantially the same time as claimed, given the single clinical analyzer employed in the Yoshida system. Absent any motivation to modify both the Yoshida rotor and the Jovanovich transport mechanism, Applicants respectfully submit that the second criterion for proving a case of obviousness has not been met.

There is no reasonable expectation of successfully modifying the cited art to produce the claimed invention

Finally, with respect to the third criterion for proving obviousness, the Office does not provide how the Yoshida and Jovanovich might successfully be combined to produce the claimed automated centrifuge systems. The Yoshida transport mechanism is designed for aspiration of individual clinical samples in (vertically-oriented) sample pots, and the Jovanovich transport mechanism also deposits the alleged “plurality of sample processing components” (capillary tubes) into microplate wells positioned on a horizontal rotor surface (such that the wells are vertically oriented). The Office has not provided how these devices could be modified and/or combined to successfully accommodate both the non-vertical clustered arrangement of sample receiving regions and the plurality of sample processing components employed. Since there is no reasonable expectation that modifying the Yoshida centrifuge rotor with the alleged plurality of Jovanovich sample processing components would successfully produce the claimed automated centrifuge systems, Applicants respectfully submit that the third criterion for proving a case of obviousness has not been met.

Summary

Since Yoshida and Jovanovich do not meet the criteria for proving a *prima facie* case for obviousness (all of the claimed elements are not taught, there is no motivation to modify the cited art, nor is there a reasonable expectation of successfully producing the claimed invention), Applicants respectfully submit that the rejection is improper and must be withdrawn.

THE CLAIMS ARE PATENTABLE OVER YOSHIDA, JOVANOVICH AND PANG

Claims 10-13, 15, 17, 18, 23 and 25-28 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Yoshida and Jovanovich in view of Pang et al. (USPN 6,060,022). Applicants traverse.

As noted above, three requirements must be met for a *prima facie* case of obviousness: the prior art reference must teach all of the limitations of the claims, there must be a motivation to modify the reference to produce the claimed invention, and there must be a reasonable expectation of success. Furthermore, the teaching or suggestion to combine and the expectation of success must be both found in the prior art and not based on Applicants' disclosure. Applicants submit that the cited art does not meet the criteria for proving a *prima facie* case for obviousness.

The rejected claims are drawn to various embodiments of the non-vertical clusters of sample receiving regions. Yoshida is alleged to teach centrifuge systems having a rotor and a singular transport mechanism; Jovanovich is alleged to teach a centrifuge system having a transport mechanism configured to move a plurality of capillary tubes to the wells of a microplate and a hanging bucket rotor with a platform to receive the microplate. Pang is alleged to teach clustered configurations. However, the cited art does not meet the criteria for proving a *prima facie* case for obviousness.

As noted above, neither Yoshida nor Jovanovich teach all of the elements of the claims; for example, neither publication teaches rotors in which the sample receiving regions are arranged in non-vertical clusters, or pluralities of sample processing components configured for insertion into sample vessels positioned in the non-vertical clusters of sample receiving regions of the claimed rotors. Pang does not remedy this deficit. Pang is alleged to teach rotors with clustered sample receiving regions; however, Pang does not teach or describe non-vertical clusters of sample regions; the Pang rotors, like those of Yoshida and Jovanovich, are hanging bucket-style rotors. Nor does Pang teach or describe pluralities of sample processing components configured for insertion into sample vessels positioned in the non-vertical clusters of the claimed rotors. Thus, the cited art (alone or in combination) do not teach the limitations of the claimed invention

Furthermore, the Office has not provided any motivation to alter the hanging-bucket type rotors of Pang, Yoshida and Jovanovich, nor is there any reasonable expectation of successfully producing the claimed invention. As noted above, there is no motivation provided (other than Applicants' specification) to replace the hanging-bucket style rotors of Yoshida, Jovanovich and Pang with rotors having non-vertical clusters of sample receiving regions, nor is there any expectation that the capillary cassette transport mechanism of

Jovanovich, which is designed to interface with microplate wells positioned on a horizontal surface (the Jovanovich microplate bucket) could successfully interface with sample vessels positioned in the non-vertical clusters of sample receiving regions as provided in the claimed invention.

Since all of the limitations of the claimed invention are not taught by the cited art, there is no motivation to modify the cited art, nor is there a reasonable expectation of successfully producing the claimed invention, Applicants submit that the cited art do not meet the criteria for proving a *prima facie* case for obviousness. Applicants respectfully submit that the rejection is improper and must be withdrawn.

CLAIM 22 IS PATENTABLE OVER YOSHIDA, JOVANOVICH AND ALAM

Claim 22 was rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Yoshida and Jovanovich in view of Alam et al. (USPN 5,792,050). Applicants traverse.

The cited art does not meet the criteria for proving a *prima facie* case for obviousness as provided above. Claim 22 is drawn to centrifuge system embodiments in which the plurality of sample processing components are sonication rods. As noted herein, neither Yoshida nor Jovanovich teach rotors having non-vertical clusters of sample receiving regions, or pluralities of sample processing components configured for insertion into sample vessels positioned in these non-vertical clusters. Alam, which is directed to the use of sonication probes in blood analysis, does not remedy this deficit. Thus, the cited art (alone or in combination) do not teach the limitations of the claimed invention.

Furthermore, Alam does not provide the motivation or reasonable expectation of success that is absent from the Yoshida and Jovanovich teachings. As noted above, the Office has not provided any motivation to replace the hanging-bucket style rotors of Yoshida and/or Jovanovich with rotors having non-vertical clusters of sample receiving regions, nor is there any expectation that the capillary cassette transport mechanism of Jovanovich, even if combined with the sonication probes of Alam, would be capable of successfully interfacing with such non-vertical clusters of sample receiving regions.

Since all of the limitations of the claimed invention are not taught by the cited art, there is no motivation to modify the cited art, nor is there a reasonable expectation of successfully producing the claimed invention, Applicants submit that the cited art do not

meet the criteria for proving a *prima facie* case for obviousness. Applicants respectfully submit that the rejection is improper and must be withdrawn.

CLAIMS 24 AND 41 ARE PATENTABLE OVER YOSHIDA, JOVANOVICH AND ROGINSKI

Claims 24 and 41 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Yoshida and Jovanovich in view of Roginski et al. (USPN 4,927,545). Applicants traverse.

The cited art does not meet the criteria for proving a *prima facie* case for obviousness. Claim 41 is drawn to centrifuge system embodiments including recognizing means and/or indexing means; the rejection of claim 29 is moot, this claim being cancelled herein. As noted above, neither Yoshida nor Jovanovich teach rotors having non-vertical clusters of sample receiving regions, or pluralities of sample processing components configured for insertion into sample vessels positioned in these non-vertical clusters. Roginski, which teaches robotic arms and barcode readers/optical sensors, does not remedy this deficit. Thus, the cited art (alone or in combination) do not teach the limitations of the claimed invention.

Furthermore, Roginski does not provide the motivation or reasonable expectation of success lacking in the Yoshida and Jovanovich teachings. As noted above, the Office has not provided any motivation to replace the hanging-bucket style rotors of Yoshida and/or Jovanovich with rotors having non-vertical clusters of sample receiving regions, and Roginski does not remedy this deficit. Furthermore, the Roginski robotic arm is designed for individual test tubes (column 4, lines 23-25: “the robotic arm 10 loads test tubes... into the centrifuge 20 one by one from the input rack 16.”), as are the optical sensor and barcode reader (see column 5, lines 4-6: “The vertical cavity 50 has an opening 54, and is adapted to receive a test tube of conventional construction”). There is no motivation to alter the Roginski robotics with respect to the non-vertical clusters of sample receiving regions and pluralities of sample processing components as claimed, or any reasonable expectation that such modification would lead to the claimed invention.

Since all of the limitations of the claimed invention are not taught by the cited art, there is no motivation to modify the cited art, nor is there a reasonable expectation of successfully producing the claimed invention, Applicants submit that the cited art do not

meet the criteria for proving a *prima facie* case for obviousness. Applicants respectfully submit that the rejection is improper and must be withdrawn.

CLAIMS 39-40 ARE PATENTABLE OVER YOSHIDA, JOVANOVICH AND TAYLOR

Claims 39-40 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Yoshida and Jovanovich in view of Taylor et al. (USPN 4,822,331). Applicants traverse.

The cited art does not meet the criteria for proving a *prima facie* case for obviousness. Claims 39-40 are drawn to centrifuge system embodiments having operator safety members. As noted herein, neither Yoshida nor Jovanovich teach rotors having non-vertical clusters of sample receiving regions, or pluralities of sample processing components configured for insertion into sample vessels positioned in these non-vertical clusters. Taylor, which allegedly teaches safety mechanisms, does not remedy this deficit. Furthermore, Taylor does not provide the motivation or reasonable expectation of success that is absent from the Yoshida and Jovanovich teachings, beyond that provided in Applicants' disclosure. Since all of the limitations of the claimed invention are not taught by the cited art, there is no motivation to modify the cited art, nor is there a reasonable expectation of successfully producing the claimed invention, Applicants submit that the cited art do not meet the criteria for proving a *prima facie* case for obviousness. Applicants respectfully submit that the rejection is improper and must be withdrawn.

CLAIMS 50-52 ARE PATENTABLE OVER YOSHIDA, JOVANOVICH AND FELDMAN

Claims 50-52 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Yoshida and Jovanovich in view of Feldman (USPN 5,445,958). Applicants traverse.

The cited art does not meet the criteria for proving a *prima facie* case for obviousness. Claims 50-52 are drawn to centrifuge system embodiments sample purification components, including but not limited to resin beds. Feldman allegedly teaches the use of liquid chromatography and nickel chelate resins for blood analysis. However, Feldmen does not remedy the deficits in Yoshida nor Jovanovich: Feldman does not teach or describe rotors having non-vertical clusters of sample receiving regions, or pluralities of sample processing components configured for insertion into sample vessels positioned in these non-vertical clusters. Furthermore, Feldman does not provide any motivation for altering the rotors of

Yoshida and/or Jovanovich, nor any reasonable expectation that the claimed invention could successfully be produced from such modification. Since all of the limitations of the claimed invention are not taught by the cited art, there is no motivation to modify the cited art, nor is there a reasonable expectation of successfully producing the claimed invention, Applicants submit that the cited art do not meet the criteria for proving a *prima facie* case for obviousness. Applicants respectfully submit that the rejection is improper and must be withdrawn.

CLAIM 113 IS PATENTABLE OVER YOSHIDA AND ROGINSKI

Claims 113 was rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Yoshida in view of Roginski. Applicants traverse.

The cited art does not meet the criteria for proving a *prima facie* case for obviousness. Claim 113 is drawn to automated centrifuge systems having a rotor with a plurality of sample receiving regions, and both a transport mechanism and a robot, the transport mechanism being configured to move one or more sample processing components proximal to or within the plurality of sample receiving regions, and the robot being capable of inserting one or more sample vessels into the sample receiving regions at substantially the same time.

Yoshida is alleged to teach a system having a centrifuge rotor with a plurality of receiving regions (sample pots) and a transport mechanism (driving device and arm) configured to move a sample take-out pipe into a sample pot. As noted in the Office Action, Yoshida does not teach or disclose robots for insertion of a sample into the centrifuge rotor. Roginski is alleged to teach robotic arms with grippers for transporting test tubes to and from a centrifuge rotor. However, neither Yoshida nor Roginski teach rotors in which the plurality of sample receiving regions are arranged in non-vertical clusters having longitudinal axes that are substantially parallel among members of a given cluster. While the Roginski rotors are fixed angle rotors, the sample receiving regions are not arranged in clusters. Furthermore, neither publication teaches or discloses pluralities of sample processing components configured for insertion into sample vessels positioned in the non-vertical clusters of sample receiving regions of the claimed rotors, or transport mechanisms coupled thereto. Since Yoshida and Roginski, alone or in combination, do not teach all of the

limitations of the claims, Applicants respectfully submit that the cited art does not meet the first criterion for proving a *prima facie* case for obviousness.

With respect to the second and third criteria for proving a *prima facie* case for obviousness, the Office has not provided any motivation for modifying the Yoshida or Roginski rotors to include clusters of sample receiving regions, or any reasonable expectation that the claimed invention would successfully be produced upon such combination. As noted previously, the Roginski robotic arm is designed for transportation of individual test tubes, not substantially simultaneous insertion of two or more sample vessels into non-vertical clusters of sample receiving regions. The Office has not provided any motivation to alter the Roginski robotics with respect to either movement of two or more sample simultaneously, or with respect to the clusters of non-vertical sample receiving regions, or any reasonable expectation that such modification would lead to the claimed invention

Since Yoshida and Roginski do not meet the criteria for proving a *prima facie* case for obviousness (all of the claimed elements are not taught, there is no motivation to modify the cited art, nor is there a reasonable expectation of successfully producing the claimed invention), Applicants respectfully submit that the rejection is improper and must be withdrawn.

CLAIM 114 IS PATENTABLE OVER YOSHIDA, ROGINSKI AND HUBERT

Claims 114 was rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Yoshida in view of Roginski and Hubert (USPN 6,589,789). Applicants traverse.

The cited art does not meet the criteria for proving a *prima facie* case for obviousness. Claim 114 is drawn to automated centrifuge systems having first rotor comprising a plurality of substantially non-vertical sample receiving regions, and either or both of a transport mechanism configured to move one or more sample processing components, and a robot capable of inserting at least two sample vessels into the sample receiving regions at substantially the same time. As noted above, neither Yoshida nor Roginski teach rotors in which the plurality of sample receiving regions are arranged in non-vertical clusters having longitudinal axes that are substantially parallel among members of a given cluster, or pluralities of sample processing components configured for insertion into sample vessels positioned in the non-vertical clusters of sample receiving regions of the claimed rotors. Yoshida figures 4 and 6 as referenced in the Office Action (page 18) are

depictions of the hanging bucket rotor with the sample pots extended (figure 4, for the purpose of clarity; figure 6, showing position during rotor rotation); these figures do not depict interaction of the sample take-out pipe with the sample pot in the depicted orientation, nor are they meant to.

The deficits in Yoshida and Roginski are not remedied by Hubert, which is alleged to teach robots that are capable of simultaneously moving a plurality of sample tubes. However, the Hubert robotic devices are designed for use with vertical sample tubes; Hubert does not teach or describe robots capable of inserting at least two sample vessels into the sample receiving regions at substantially the same time, wherein the sample receiving regions comprise one or more non-vertical clusters.

Furthermore, with respect to the second and third criteria for proving a *prima facie* case for obviousness, the Office has not provided any motivation for modifying the Hubert robotics to interact with non-vertical sample receiving regions, or for modifying the Yoshida or Roginski rotors to include clusters of sample receiving regions, or any reasonable expectation that the claimed invention would successfully be produced upon such combination.

Since Yoshida, Roginski and Hubert (alone or in combination) do not meet the criteria for proving a *prima facie* case for obviousness (all of the claimed elements are not taught, there is no motivation to modify the cited art, nor is there a reasonable expectation of successfully producing the claimed invention), Applicants respectfully submit that the rejection is improper and must be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the claims are deemed not to be in condition for allowance after consideration of this Response, a telephone interview with the Examiner is hereby requested.

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Respectfully submitted,



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Attachments:

- 1) A Request for Continued Examination;
- 2) IDS and accompanying Form 1449;
- 3) A petition to extend the period of response for 5 months;
- 4) A transmittal sheet;
- 5) A fee transmittal sheet; and,
- 6) A receipt indication postcard.